

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In re: BAIR HUGGER FORCED AIR  
WARMING DEVICES PRODUCTS  
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

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This Document Relates To:  
*All Cases*

**PLAINTIFFS' MEMORANDUM IN  
SUPPORT OF PLAINTIFFS'  
MOTION TO EXCLUDE OPINIONS  
AND TESTIMONY OF  
ALEXANDER A. HANNENBERG,  
M.D.**

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Pursuant to Federal Rules of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Plaintiffs respectfully move this Court to exclude the report and testimony of Defendants' expert witness Dr. Hannenberg.

## **I. INTRODUCTION**

"[T]he district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.'" *Belk, Inc. v. Meyer Corp.*, U.S., 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156 (1999)).

Dr. Hannenberg is an anesthesiologist who retired from practice in 2017. His entire experience with patient warming has consisted of using the Bair Hugger to regulate patient temperatures during various surgeries during his career and some selected review of literature that he conducted. He has no special expertise in arthroplasty surgeries, device warnings, infectious diseases, the importance of normothermia, or study design. All of his opinions are actually just personal opinions based solely on a review of selected literature and his wholesale acceptance of the views of certain medical organizations.

Dr. Hannenberg offers no methodology, much less an accepted scientific methodology, for his opinions. The trial court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *See Kumho Tire Co. Ltd., v. Carmichael*, 526 U.S. 137, 152 (1999).

Here, however, Dr. Hannenberg never describes in his report any methodology, much less a scientifically accepted methodology, that he used to render his opinions. (Ex. A – Expert Report).<sup>1</sup> Further, Dr. Hannenberg frequently failed, during his deposition, to have actually reviewed or considered studies, depositions, and internal documents that are relevant to his opinions, nor, even for those documents he did review, to be able to recall the details of those documents. To make matters worse, Dr. Hannenberg’s list of materials reviewed and relied on was admittedly incomplete and, unlike his normal practice as a physician, he took no notes during his literature review, leaving no method to determine what materials Dr. Hannenberg actually reviewed, considered, relied on, failed to review, and/or discarded.

Dr. Hannenberg claims to render numerous opinions, but does not establish through his report, or even through his deposition, why he is qualified to render such opinions, nor does he describe the methodology he used to arrive at those opinions. Dr. Hannenberg has clearly failed to apply the same level of intellectual rigor to his opinions in this litigation as an expert in the relevant field would. For those reasons and others, as described in more detail below, Plaintiffs respectfully submit that Dr. Hannenberg, the opinions proffered in his report, and any testimony proffered, should be excluded.

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<sup>1</sup> All references to Ex. \_\_ are references to exhibits to the Declaration of Genevieve M. Zimmerman in Support of Plaintiffs’ Motion to Exclude the Opinions and Testimony of Alexander A. Hannenberg, M.D., filed concurrently herewith.

## II. LEGAL STANDARD

Federal Rule of Evidence 702 permits expert witnesses to testify if the subject of their testimony is relevant, the witnesses are qualified to express their opinions, and the proposed evidence upon which they base their testimony is reliable or trustworthy. *Polski v. Quigley Corp.*, 538 F.3d 836, 839 (8<sup>th</sup> Cir. 2008).

Courts are the gatekeeper of evidence proffered under Rule 702, “to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co.*, 526 U.S. at 152.

Expert testimony must be trustworthy for it to be reliable. *Daubert*, 509 U.S. at 590. The Eighth Circuit considers additional factors as well, including: “whether the expertise was developed for litigation or naturally flowed from the expert’s research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case. *Polski*, 538 F.3d at 839. The party seeking admission of expert testimony has the burden of demonstrating its reliability. *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007).

A “very significant” criterion for reliability is whether the expert’s testimony is based on research independent of litigation. *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9<sup>th</sup> Cir. 1995) (*Daubert II*). “If the proffered expert testimony is not based on independent research, the party proffering it must come forward with other objective, verifiable evidence and explain precisely how they went about reaching their

conclusions and point to some objective source – a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like – to show that they have followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in their field.” *Id.*, 43 F.3d at 1317-19.

Where the factual basis, data, or the methodology employed by the expert are sufficiently called into question, the court must determine not only if the testimony is reliable, but also whether it has a valid connection to the pertinent inquiry. *Kumho Tire Co.*, 526 U.S. at 149. Expert testimony must therefore “logically advance[] a material aspect of the proposing party’s case.” *Daubert*, 509 U.S. at 597. The court should not admit opinion evidence “that is connected to existing data only by the *ipse dixit* of the expert,” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997), or that is based on his own unique methodology rather than a respected methodology. *Groobert v. President and Directors of Georgetown College*, 219 F. Supp. 2d 1 (D.D.C. 2002). Under these circumstances, a court may conclude there is simply too great an analytical gap between the data and the opinion.” *Gen. Elec. Co.*, 522 U.S. at 146.

### **III. ARGUMENT**

Dr. Hannenberg claims, in his expert report, to render the following opinions:

1. Optimal patient care in arthroplasty surgery includes forced air warming;
2. Clinical tactics can mitigate the risk of surgical infection;
3. Theoretical concerns associated with forced air warming disrupting laminar flow are irrelevant and based on invalid experimental models;

4. Impartial and authoritative review of warming technology supports the safety of forced air warming;
5. Cardiovascular heater-cooler device issues are not relevant to forced air warming technologies; and
6. The Bair Hugger's labeling and design were reasonable.

He then claims to reach the following conclusions:

1. Normothermia reduces surgical site infections;
2. Forced air warming devices safe and efficacious;
3. Bair Hugger labeling is reasonable and does not need to include warning of the risk of surgical site infections;
4. The Bair Hugger does not cause surgical site infections;
5. Studies addressing disruptions in laminar flow or increased airborne particle counts do not demonstrate an increase in frequency of clinical infections.

None of these opinions and conclusions, however, are supported by any special expertise that he has, nor are they supported by any scientific methodology.

**A. Dr. Hannenberg Has No Special Expertise In The Subjects On Which He Seeks To Give Opinions**

Dr. Hannenberg was a practicing anesthesiologist. He admits that he has no expertise in normothermia other than simply using a Bair Hugger to manage patient body



temperatures. (Dep. at 27:20-29:22)<sup>2</sup> The sole basis for his opinions regarding the importance of normothermia come from his review of selected literature and references. *Id.* He readily admits that both Dr. Kurz<sup>3</sup> and Dr. Sessler<sup>4</sup> are experts in the field, and concedes he does not have their expertise. *Id.* He also readily admits that he has done no clinical research on normothermia and has not published any studies or papers related to thermoregulation or normothermia. *Id.* Rather, the overwhelming majority of his publications have related to the topics of pay-for-performance and the economics of anesthesiology, neither of which are relevant to this litigation or his proffered opinions. (Dep. 75:1 to 76:2; 78:24-95:20)

Dr. Hannenberg also admits has no experience with the design or regulation of medical devices. (Dep. 68:13-68:18). He admits that he has done no research with regard to surgical site infections. (Dep. 107:8-108:7) He admits he is not an infectious diseases expert. *Id.* He admits he is not an orthopedic expert. *Id.* He admits he is not an internal medicine expert. *Id.* He admits he is not an airflow expert. *Id.* He admits he is not a

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<sup>2</sup> All references to “Dep. [page]:[line]” are to page and line numbers of the Deposition of Alexander A. Hannenberg taken on August 8, 2017, relevant excerpts of which are attached as Ex. C to the Zimmerman Declaration in Support filed concurrently herewith. All references to “Dep. Exh. \_\_\_” are to exhibits to the Hannenberg deposition, attached as Ex. D to the Zimmerman Declaration.

<sup>3</sup> Dr. Andrea Kurz was the lead author of the 1996 study which is the origin of the concept that maintaining normothermia during surgery may reduce the risk of infection. Dr. Kurz was deposed as a third-party witness in this MDL.

<sup>4</sup> Dr. Daniel Sessler was a co-author of the 1996 Kurz study, was a leading proponent of normothermia, and consulted with 3M regarding the Bair Hugger device. Dr. Sessler has been deposed three times in the context of this litigation, initially in the Walton and Johnson cases, and now in this MDL.

filtration expert. *Id.* He admits he has no experience with the 510(k) approval process. (Dep. 140:3-141:23) He admits that he has never created or designed a medical device. *Id.* He admits he has never consulted on what warnings should be on a medical device. *Id.* He admits he has never written a warning with regard to anything, much less a medical device. *Id.* He admits that the only basis for any opinion he gives regarding warnings is from the perspective of him as an end user. *Id.* He admits he is not an expert in airborne contamination. *Id.* He admits he is not an expert on forced-air warming devices. *Id.* He admits that he is not an expert in study design. (Dep. 135:12-136:4) He admits he has never studied the causes of periprosthetic joint infections. (Dep. 258:18 to 258:25)

Dr. Hannenberg states that his opinions are based on his literature review and his clinical experience, however, he admits that as an anesthesiologist, he does not personally follow up with any of his patients and, therefore, can have no idea whether any of his patients developed a periprosthetic joint infection after surgery. (Dep. 119:22 to 120:17) He further admits that his sole experience with thermoregulation devices is with the Bair Hugger, and he has never tried or used any other type of warming blanket or device, though he is aware there are multiple modalities for keeping a patient normothermic. (Dep. 96:22 to 98:13).

Dr. Hannenberg also admits he is not an expert in heat transfer. (Dep. 245:8 to 245:25) He admits he is not an expert in fluid dynamics. *Id.* Dr. Hannenberg admits that he has no opinion with respect to how the Bair Hugger blanket may affect the OR environment by the heat it produces or the airflow it produces. (Dep. 204:4-206:4)

In light of all of these admissions, Dr. Hannenberg should not be permitted to offer testimony about the risk of infection, the sufficiency of the warnings on any medical device, including the Bair Hugger, nor any of the other subjects upon which he seeks to opine. Put simply, Dr. Hannenberg is the wrong person to attempt to render the opinions that he does, because he admits he lacks the requisite expertise to render those opinions. This admitted lack of expertise, alone, should exclude Dr. Hannenberg's report and opinions in their entirety.

**B. Dr. Hannenberg Fails To Identify And/Or Adhere To Any Scientific Methodology**

Dr. Hannenberg never discusses in his report any methodology, much less a scientifically accepted methodology, that he uses to render his opinions. (Ex. A) During his deposition Dr. Hannenberg repeatedly failed to demonstrate whether he actually reviewed studies, depositions, or internal documents relevant to his proffered opinions. Even for those documents he did review, Dr. Hannenberg was unable to remember the details of those documents. To make matters worse, Dr. Hannenberg's list of materials reviewed and relied on was admittedly incomplete, leaving no method of determining what materials Dr. Hannenberg actually reviewed, relied on, failed to review, and/or discarded, and providing no reliability in support of the opinions Dr. Hannenberg hopes to offer. (Dep. 30:5-31:18; 48:9-50:17)

At numerous times during his deposition, Dr. Hannenberg was asked what materials he had reviewed, considered, or relied upon, but was unable to give definitive answers. Although he provided a list of materials that purportedly served as the basis for

the opinions in his report (Ex. A p. 8 at Footnotes 1-21; Ex. B; Dep. Exh. 1 and 2) he also testified at deposition that he considered Dr. Wenzel's, Dr. Mont's, and Dr. Keuhn's reports, an unidentified "video of airflow," an unidentified "testing report regarding filtration," and parts of Dr. Kurz's deposition, all of which Dr. Hannenberg claims he relied upon in drafting his expert report. (Dep. 30:5-31:18). He also testified that he viewed "trade publications" and an e-mail, but did not keep a record of those publications. *Id.*

Dr. Hannenberg testified it was his normal custom to make and keep written notes while he practiced medicine. (Dep. 48:9-50:17) Despite this normal habit, Dr. Hannenberg testified he failed to follow his normal practice as a doctor and took no notes during his review of materials and preparation of his report. *Id.* The reason? Hannenberg explained his departure from his own custom and practice was instruction from counsel not to take notes. *Id.* He further testified that he did not remember which depositions or documents he had read, but that if he had taken notes, he would have a record of what, exactly, he had reviewed. *Id.* For example, Dr. Hannenberg claimed at deposition to have reviewed a deposition of Dr. Sessler, but no Sessler transcript is included in the list of materials he reviewed, nor could Dr. Hannenberg could remember which parts of which Sessler transcript he considered, or when he reviewed it. (Dep. 41:24-42:21)

Thus, as a preliminary matter, there is no record of the documents and testimony which Dr. Hannenberg considered to arrive at his opinions. The failure to provide a complete disclosure of documents considered and relied upon in forming expert opinions could alone, make any opinions he intends to render methodologically unsound. Dr.

Hannenbergs testified that he was provided over a hundred documents by 3M's attorneys, but that he did not review all of them, and has no idea how many or which of those he did review. (Dep. 108:25-109:18) Further, Dr. Hannenberg testified that he reviewed depositions, but then stated that "which ones [he reviewed], and which ones [he] relied on the expert reports, [he is] not able to say." (Dep. 15:21-25) On one point, however, Dr. Hannenberg was clear – that there were numerous relevant studies, documents and testimony that Dr. Hannenberg did not consider in arriving at his opinions:

- Dr. Hannenberg stated that he relied on the conclusion of a Memarzadeh letter to the editor, but failed to review the underlying computational fluid dynamics analysis done by Memarzadeh and further admitted that he would not understand the underlying computational fluid dynamics analysis even had he reviewed it (Dep. 297:8-298:5);
- Dr. Hannenberg is neither aware of nor does he accept the finding of the International Consensus agreeing that there is a theoretical risk that the Bair Hugger can cause surgical site infections (Dep. 303:14-303:22);
- Dr. Hannenberg failed to consider the Huang paper in formulating his opinion for the expert report (Dep. 31:24-36:5);
- Dr. Hannenberg failed to consider the Zink paper in formulating his opinion for the expert report (Dep. 31:24-36:5);
- Dr. Hannenberg failed to consider the Moretti paper in formulating his opinion for the expert report (Dep. 31:24-36:5);

- Dr. Hannenberg failed to consider the Sun/Kurz paper in formulating his opinion for the expert report (Dep. 31:24-36:5);
- Dr. Hannenberg failed to consider the Sessler/Olmstead/Kuplinger paper in formulating his opinion for the expert report (Dep. 31:24-36:5);
- Dr. Hannenberg failed to consider the Belani paper “Patient warming excess heat: The effects on orthopedic operating room ventilation on performance” in formulating his opinion for the expert report (Dep. 31:24-36:5);
- Dr. Hannenberg failed to consider the Reed paper in formulating his opinion for the expert report (Dep. 31:24-36:5);
- Dr. Hannenberg considered only one of the Legg papers in formulating his opinion for the expert report, a paper which he found on a website. (Dep. 31:24-36:5);
- Dr. Hannenberg failed to consider the Stocks paper on particles in formulating his opinion for the expert report (Dep. 31:24-36:5);
- Dr. Hannenberg failed to consider the Darouiche paper on particles and bacterial load in formulating his opinion for the expert report (Dep. 31:24-36:5);
- Dr. Hannenberg failed to consider the Albrecht paper “Forced air warming: A source of airborne contamination in the operating room” in formulating his opinion for the expert report (Dep. 31:24-36:5);

- Dr. Hannenberg failed to consider the Tjoakarfa paper “Reflective Blankets Are as Effective as Forced Air Warmers in Maintaining Normothermia During Hip and Knee Arthroplasty Surgery” in formulating his opinion for the expert report (Dep. 196:20-197:25);
- Dr. Hannenberg failed to consider the Brandt paper “Resistive-Polymer Versus Forced-Air Warming: Comparable Efficacy in Orthopedic Patients” in formulating his opinion for the expert report (Dep. 203:10-204:3);
- Dr. Hannenberg failed to consider the later published (2017) Frisch paper, while considering an earlier published paper by the same author, in formulating his opinion for the expert report (Dep. 208:18-210:12; 212:18-213:6);
- Dr. Hannenberg failed to review the deposition of Gary Maharaj (Dep. 41:24-44:11);
- Dr. Hannenberg failed to review the deposition of Teri Sides (Dep. 41:24-44:11);
- Dr. Hannenberg failed to review the deposition of Karl Zgoda (Dep. 41:24-44:11);
- Dr. Hannenberg failed to review the deposition of Gary Hansen (Dep. 41:24-44:11);
- Dr. Hannenberg failed to review the deposition of Troy Bergstrom (Dep. 41:24-44:11);

- Dr. Hannenberg failed to review the deposition of David Westlin (Dep. 41:24-44:11);
- Dr. Hannenberg failed to review the deposition of Dan Koenigshofer (Dep. 41:24-44:11);
- Dr. Hannenberg failed to review the deposition of Mike Buck (Dep. 41:24-44:11);
- Dr. Hannenberg failed to review the deposition of Dr. Elgobashi (Dep. 41:24-44:11);
- Dr. Hannenberg failed to review the deposition of Dr. Jarvis (Dep. 41:24-44:11);
- Dr. Hannenberg failed to review the deposition of Dr. Stonnington (Dep. 41:24-44:11);
- Dr. Hannenberg failed to review the deposition of Dr. Wenzel (Dep. 26:18-27:12);
- Dr. Hannenberg failed to review the deposition of Dr. Kuehn (Dep. 26:18-27:12);
- Dr. Hannenberg failed to review the deposition of Dr. Mont (Dep. 26:18-27:12);
- Dr. Hannenberg does not know whether he reviewed the deposition of Al Van Duren (Dep. 26:18-27:12);and
- Dr. Hannenberg failed to consider *any* internal 3M documents (Dep. 55:1-56:15).



Dr. Hannenberg admits that the only “methodology” he followed was the (flawed) literature review described above, which apparently consisted primarily, if not solely, of a review of materials identified and/or provided to him by counsel for Defendants<sup>5</sup>, together with his own clinical experience. (Dep. 278:3-282:16) Dr. Hannenberg further admitted, with regard to his review of materials, that:

What I’ve been saying is that I’ve reviewed materials in various – in various formats from various sources. My – whatever opinion I hold – hold today is the result of the sum of that information, ***and I have not really made an effort to connect an opinion with whether it is directly derived from a particular document.***

(Dep. 20:18-24) (emphasis added)

Further, with regard to his own clinical experience, Dr. Hannenberg admits that he has personally done no study or research to determine whether normothermia reduces the rate of surgical site infections. *Id.* He also admits that he does not follow up with any patients to determine whether or not they suffered from a surgical site infection after surgery. *Id.*

In fact, Dr. Hannenberg admits, in a telling deposition question and answer, that without the literature review, he has no basis at all upon which to opine that the Bair Hugger is safe:

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<sup>5</sup> At no point in his report or deposition does Dr. Hannenberg even mention what independent search for literature, *if any*, he conducted, much less any methodology he employed in conducting such search.

Q: What about your experience, education, training, about you, doctor, gives you the expertise to determine whether or not the Bair Hugger has any effect on the airflow that could increase the bacterial load over the surgical site?

A: I have said multiple times I am not an expert in bacterial load over the – over the surgical site.

Q: So I'm just trying to figure out – Forget about the literature.

***Without the literature, you actually have no methodology to offer the opinion that the Bair Hugger does not increase the bacterial load over the surgical site and is safe.***

***A: That's – that's – that's corr – correct. I've already said that.***

(Dep. 288:11-289:4) (emphasis added).

In fact, Dr. Hannenberg goes even further and admits that even his own (flawed) literature review is not the primary basis for his opinions, but rather, that he “*heavily relied*” on the findings of groups such as ECRI, NICE, and the physicians consortium, and that those findings have been “*very persuasive* in [his] decision making.” (Dep. 151:15-152:24) (emphasis added)

Given Dr. Hannenberg's admissions regarding his lack of expertise in numerous subject areas upon which he tries to opine, and his admissions regarding his complete failure to conducted any independent study or research on the topics on which he seeks to render an opinion, there is actually nothing in Dr. Hannenberg's clinical experience that allows him to render his reliable, helpful opinions to the jury in this case. Thus, Dr.

Hannenbergs sole source for his opinions is the methodologically flawed literature review described above, an ill-defined literature review he did not have any special expertise to do, having admitted that he has no experience in study design. (Dep. 135:12-136:4)

Thus, Dr. Hannenberg proffers no methodology, much less a scientifically valid methodology, for the opinions that he seeks to offer. The sole basis for his opinions consist of his incomplete literature review. However, there is nothing in Dr. Hannenberg's background or experience that allows him to properly conduct a literature review and opine on its results as an expert any more than any medical resident, doctor, lawyer, statistician or, for that matter, a layperson could do.

Dr. Hannenberg clearly did not arrive at the opinions expressed in his report with the "same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *See Kumho Tire Co.*, 526 U.S. at 152. Dr. Hannenberg and his proffered opinions should be excluded in their entirety.

**C. Dr. Hannenberg Fails To Support His Individual Opinions**

In addition to the overall lack of expertise and methodology, many of Dr. Hannenberg's individual opinions and conclusions suffer from additional flaws.

**1. Hannenberg Offers No Support for his Contention that Optimal patient care in arthroplasty surgery includes forced air warming;**

Dr. Hannenberg claims to opine in this section of his report that normothermia results in less surgical site infections in arthroplasty cases, that the most effective method of maintaining normothermia is by using forced air warming, and that the Bair Hugger is

a safe and efficacious device. (Ex. A pp. 2-3) He similarly states in his conclusions that maintaining normothermia reduces the risk of surgical site infections, and that forced-air warming devices, and the Bair Hugger in particular, are safe and efficacious. (Ex. A pp. 6-7) Other than citing to reports issued by other groups such as ECRI, however, Dr. Hannenberg's deposition testimony shows that he has no support for his proffered opinions and conclusions.

On the topic of normothermia, during his deposition, Dr. Hannenberg admitted that one of the studies he purportedly relied on, the Scott study,<sup>6</sup> confirms there is no statistically significant difference in the use of a warming device or no warming device on surgical site infections. (Dep. 156:11-163:2) Dr. Hannenberg also admitted that the Melling<sup>7</sup> study on which he relied was limited to pre-operative warming and therefore could not shed any light on intra-operative warming. (Dep. 163:19-165:20) Dr. Hannenberg also agreed that even in actively warmed patients, hypothermia is routine during the first hour of anesthesia. (Dep. 155:17-156:10) Finally, despite admitting that Dr. Kurz is much more of an expert in normothermia than he is, he claimed that he disagreed with Dr. Kurz that "there is no reliable evidence that support ... maintaining normothermia reduces the incidences of infection." (Dep. 173:11-175:5) However, when asked the basis for his disagreement, the *only* studies he could cite to were Dr. Kurz's

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<sup>6</sup> Dep. at Exh. 8

<sup>7</sup> Melling A., et al., *Effects of preoperative warming on the incidence of wound infection after clean surgery: a randomised controlled trial*, LANCET. 2001 Sep. 15;358(9285):876-80

own study<sup>8</sup> and the Melling study, which he previously admitted only dealt with pre-operative warming and not intra-operative warming. (Dep. 173:11-175:5; 163:19-165:20)

On the topic of forced-air warming being a superior warming method, during his deposition Dr. Hannenberg admitted that *he has never used any other form of warming*. (Dep. 96:22 to 98:13) Dr. Hannenberg also, crucially, admitted that he has “*no fact or science*” to support his opinion that forced-air warming is more effective than reflective blanket warming, and failed to even consider the Tjoakarfa study<sup>9</sup> that found reflective blankets to be just as effective as forced-air warming in maintaining normothermia during hip and knee arthroplasty surgeries. (Dep. 196:20-197:25) **Dr. Hannenberg, finally, was forced to admit that despite the opinion he attempted to express in his report, that he actually has no opinion on whether the Bair Hugger is safer or less safe than other devices**, and has done no research or even review of literature regarding comparable products. (Dep. 198:1-198:9; 203:10-204:3) Given this striking admission, Dr. Hannenberg should be barred from offering any opinion or testimony that the Bair Hugger is safe and efficacious.

On the topic of safety, Dr. Hannenberg admitted that he has never had any discussions with orthopedic surgeons regarding whether or not they look unfavorably with respect to particles over the surgical wound site (Dep. 140:3-141:23); does not know

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<sup>8</sup> Kurz A., et al., *Perioperative normothermia to reduce the incidence of surgical infection and shorten hospitalization*, N ENGL J MED.(1996;334:1209 )15 -wound

<sup>9</sup> Tjoakarfa C., *Reflective Blankets Are as Effective as Forced Air Warmers in Maintaining Patient Normothermia During Hip and Knee Arthroplasty Surgery*. J ARTHROPLASTY (2017 Feb;32(2):624-627).

how many bacteria or CFUs are needed to cause a periprosthetic joint infection, nor whether that number is more or less than the number of bacteria or CFUs needed to cause a surgical site infection. (Dep. 135:12-136:4); and that he is not qualified to draw a connection between a finding of the Bair Hugger increasing the bacterial load over a surgical site and the risk of using the Bair Hugger. (Dep. 134:11-135:1)

Further, although part of the basis for Dr. Hannenberg's opinion on the safety of the Bair Hugger device is Dr. Hannenberg's statement in his report that the rate of infection at the Newton-Wellesley hospital at which he practices, and which exclusively uses Bair Huggers for intraoperative patient warming, has been 0.6 percent, Dr. Hannenberg admitted that the Hospital Compare report issued by Medicare listed the national rate of complications for hip/knee replacement at 2.8 percent, and stated that specifically for Newton-Wellesley hospital, that the rate was "*no different than the national rate.*" (Ex. A p. 2; Dep. 125:22-127:3; Dep. Exh. 6) Dr. Hannenberg did not provide in his report, and was unable to provide at deposition, any documentation to support the 0.6 percent infection rate at Newton-Wellesley hospital claimed in his report.

Thus, in addition to the lack of expertise and methodology, Dr. Hannenberg's opinions regarding the efficacy of normothermia in reducing surgical site infections, the supposed superiority of forced-air warming, and the Bair Hugger in particular, in maintaining normothermia, and the safety of the Bair Hugger, are all contradicted or found unsupported by Dr. Hannenberg's admissions during his deposition.

**2. Hannenberg is Unqualified to Conclude which Clinical Tactics may mitigate the risk of surgical infection;**

As discussed above, Dr. Hannenberg has no special expertise regarding this topic. Further, the fact that other measures can and are taken to reduce surgical site infections is undisputed and agreed to by all parties and experts. There is nothing about his opinion on this issue that would be helpful to the fact finder that is not already covered by numerous other qualified experts. Further, with respect to his sub-opinion that maintaining normothermia is important to reducing surgical site infections, the same lack of rigor in his opinions as discussed immediately above applies here. Under the relevant case law, unreliable and irrelevant information must be kept from the trier of fact because of its inability to assist in factual determinations, its potential to create confusion, and its lack of probative value. *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1312 (11th Cir. 1999). Nothing Dr. Hannenberg offers in this section will help the trier of fact.

**3. Hannenberg Offers No Basis for his Conclusion that Theoretical concerns about forced air warming disrupting laminar flow are irrelevant and based on invalid experimental models**

As discussed above, Dr. Hannenberg has absolutely no expertise in any of the fields that would allow him to opine on the topic of forced air warming's effects on the air flow in an operating room, nor on the conclusions he draws from that opinion, namely, that the Bair Hugger does not cause surgical site infections, and that disruptions in in laminar flow or increased particle count do not demonstrate an increased frequency of infection.

The only basis for Dr. Hannenberg's opinions are limited articles to which he cites and his anecdotal experience that he feels hot air coming out of his patient's head and neck areas when using Bair Hugger upper body blankets. That is not sufficient to qualify him as an expert, nor to provide the finder of fact with reliable scientific opinions.

Importantly, one of the critiques that Dr. Hannenberg levels at Plaintiffs' studies is that they do not include real people and additional equipment, however, Dr. Hannenberg admits that he has no idea whether having real people and additional equipment in the experimental models that he critiques for not having those would increase or decrease the particles shown in those tests. (Dep. 110:1-111:9) Further, as previously discussed, he never even reviewed Dr. Elghobashi's report or deposition, and he professed that even for the articles he reviewed regarding computational fluid dynamics models, such as Memarzadeh, he would not understand the underlying study even had he reviewed it. (Dep. 41:24-44:11; 297:8-298:5)

Dr. Hannenberg also opines that particle counts and bubbles are poor proxies or surrogates for the risk of infection. (Dep. 246:25-257:7) However, he opines this while having never reviewed or considered two crucial studies regarding particle counts and infections, the Darouiche study<sup>10</sup> and the Stocks<sup>11</sup> study. (Dep. 246:25-249:11). In fact,

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<sup>10</sup> Darouiche R., et al., *Association of Airborne Microorganisms in the Operating Room With Implant Infections: A Randomized Controlled Trial*, INFECT CONTROL HOSP EPIDEMIOL (2017 Jan;38(1):3-10).

<sup>11</sup> Stocks G., et al., *Predicting bacterial populations based on airborne particulates: a study performed in nonlaminar flow operating rooms during joint arthroplasty surgery*, AM J INFECT CONTROL (2010 Apr;38(3):199-204).



Dr. Hannenberg was unaware that the Darouiche study correlated bacterial load over the surgical site with periprosthetic joint infection. *Id.* Dr. Hannenberg further admitted *that such a study might change his opinion* with regard to bacterial load causing periprosthetic joint infection, but that he could not tell without fully reviewing the study, and it would also depend on determining whether or not the details of the study were items which he could intelligently assess based upon his background and experience. *Id.*

Importantly, in personally discounting the importance of particle counts, Dr. Hannenberg admits he never had any discussions with orthopedic surgeons, the doctors actually following up with and having to deal with the effects of periprosthetic deep joint infections, regarding whether or not the orthopedic community looks unfavorably with respect to particles over the surgical wound site. (Dep 140:3-141:23). He admits that he, personally, has no knowledge of the prevalence of surgical site infections in his own surgeries, as he does not do any follow-up to allow him to make such a determination. (Dep. 119:22 to 120:17)

He further admits key lapses of knowledge, such as not knowing how many bacteria or CFUs are needed to cause a periprosthetic joint infection, or whether that number is more or less than the number of bacteria or CFUs needed to cause a superficial surgical site infection, and concedes he has never studied the cause of periprosthetic joint infections. (Dep. 135:12-136:4; 258:18 to 258:25) Belying his opinions in his report, Dr. Hannenberg also admits that he is not qualified to draw the connection between a finding of the Bair Hugger increasing the bacterial load over a surgical site and the risk of using the Bair Hugger. (Dep. 134:11-135:1)

Finally, Dr. Hannenberg admits that he does not know the effect of heat around the operating table on the sterility of the surgical site, nor has he ever reviewed the Brandt<sup>12</sup> study that shows that operating a Bair Hugger can raise the temperature around the patient by between 5-10 degrees Celsius. (Dep. 204:4-206:4).

Given these large, admitted, gaps in Dr. Hannenberg's knowledge, and his admitted inability to understand the underlying data on which he bases some of his opinions, Dr. Hannenberg is neither qualified to, nor properly supports, the opinions he reaches in this section of his report. Dr. Hannenberg is similarly unqualified to offer the opinion that the Bair Hugger does not cause surgical site infections, and has neither the training or experience to reach any conclusion with respect to the impact of known, admitted disruptions in laminar flow or increased particle counts associated with use of the Bair Hugger device, much less the relevance of an increased particle count *vis a vis* the increased frequency of periprosthetic joint infection.

#### **4. Hannenberg has No Reliable Basis to Conclude which Studies are Impartial and/or authoritative**

In this section, all Dr. Hannenberg does is cite to or quote publications of certain groups, such as ECRI and the International Orthopedic Consensus Meeting, and his review of some websites that he claims are associated with the Hot Dog warming system. (Ex. A p. 5) Similarly, in his conclusion, Hannenberg states that the practice of using forced air warming in surgical patient care is endorsed by numerous groups. (Ex. A p. 6)

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<sup>12</sup> Dep. Exh.14

Any finder of fact is equally capable of reviewing those publications and websites and drawing their own conclusions. Nothing in this section is really even an opinion by Dr. Hannenberg, and certainly nothing that he says requires from an individual more than the ability to read. Under such circumstances, his “opinions” in this section contain information that does not require expert gloss, and should be excluded. *See*, Fed. R. Evid. 702 Advisory Committee Notes (noting “There is no more certain test for determining when experts may be used than the common sense inquiry whether the untrained layman would be qualified to determine intelligently and to the best possible degree the particular issue without enlightenment from those having a specialized understanding of the subject involved in the dispute.” Ladd, *Expert Testimony*, 5 Vand.L.Rev. 414, 418 (1952).)

**5. Hannenberg is Unqualified to Determine Cardiovascular heater-cooler device issues are Irrelevant to forced air warming technologies;**

Dr. Hannenberg has admittedly no expertise in the study of infectious diseases, nor is there anything in his background regarding research into vectors for contamination of surgical sites that could support his opinion that the heater-cooler device issues are irrelevant to forced-air warming technologies. (Dep. 107:8-108:7) Dr. Hannenberg further tries to muddle the issue by claiming, *without any expertise, basis, or support at all*, that because the pathogen from the heater-cooler device was carried on water vapor, that it is somehow distinguishable from other forms of aerosolization or airborne contamination. Under the relevant case law, unreliable and irrelevant information must be kept from the trier of fact because of its inability to assist in factual determinations, its

potential to create confusion, and its lack of probative value. *Allison*, 184 F.3d at 1312. This section of Dr. Hannenberg's report should be excluded.

**6. Hannenberg is Unqualified to Render Opinions Regarding the Bair Hugger's labeling and design**

Dr. Hannenberg attempts to opine that the labeling of the Bair Hugger without a warning of the risks of infection was appropriate. (Ex. A p. 6) He similarly states in his conclusions that the Bair Hugger labeling was reasonable and did not need to include a warning of the risk of surgical site infection. *Id.*

Dr. Hannenberg admits, however, that he has never created a warning for a medical device. (Dep. 273:5-274:16) He also admits that he has never even reviewed the warnings of the 200 series, 500 model, or 700 series devices, never considered the operating manual for any Bair Hugger for purposes of his opinions, failed to review any of the 510(k)s for any model of Bair Hugger, and completely ignored warnings provided by other forced-air warming devices, including not being familiar with the warning on the Mistral forced-air warming device that specifically warns regarding potential airborne contamination. (*Id.*; Dep. 200:6-201:22) It is nothing short of inconceivable to attempt to offer an expert opinion on the adequacy of a warning he never read.

The only basis for Dr. Hannenberg's opinion that the labeling and design were reasonable is his opinion on the ultimate issue: that there is no risk of infection caused by the Bair Hugger. However, as discussed above, Dr. Hannenberg lacks the expertise or appropriate methodology to support this opinion. At bottom, the only opinion Dr. Hannenberg renders in this section, and in his conclusion concerning warnings, is that

because of his previous opinion that the Bair Hugger carries no risk for infection, no warning of a risk for infection is necessary. This is not a proper opinion for expert testimony and should be excluded. *See*, Fed. R. Evid. 702 Advisory Committee Notes.

#### **IV. CONCLUSION**

For the reasons discussed above, Plaintiffs respectfully submit that Dr. Hannenberg, his report, and any testimony that he seeks to offer, be excluded in their entirety.

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Respectfully submitted,

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